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March 16, 2000

Dr. Andrew Beaulieu, Deputy Center Director CVM HFV2 7500 Standish Pl. Rockville, MD 20855

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Dear Dr. Beaulieu:

I have submitted evidence to FDA that Monsanto created "freak" amino acids during the manufacturing process for the genetically engineered bovine growth hormone. In 1992, Monsanto learned of those mistakes and took eighteen months to develop a filtration process, which filtered out the "freak amino acids," and, in doing so, changed the formula for their hormone.

I filed a Freedom of Information Act request for any correspondence between Monsanto and FDA regarding those errors and change in formula. That Freedom of Information Act (FOIA) request (file #F99-26306) revealed:

"A thorough search of CVM's files has been conducted, and no records responsive to your request have been found."

Today, I spoke to Gary Barton, Monsanto's official spokesman for the bovine growth hormone. I asked him to comment on the fact that Monsanto created five "freak" amino acids during the manufacture process of the bovine growth hormone, and never revealed those errors to the Food & Drug Administration. I told Barton that the FOIA request revealed that there was absolutely no communication between Monsanto and FDA. I asked Barton for his comments. Here is Monsanto's official position:

"Monsanto, in the process of obtaining regulatory approval for bovine somatotropin, has supplied complete and accurate data to the FDA and other regulatory agencies."

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It should be clear to all parties that Monsanto made errors, changed the formula, did not inform the FDA, published the evidence, and is still in denial. Monsanto's fraud and deception is an insult to both FDA and the American people.

Very truly yours,

Robert Cohen

RC/am

cc: Gary Barton, Monsanto

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Dr. Jane Henney, Commissioner of the FDA

Dr. Marcia Larkins, CVM Ombudsman

Dr. Claire Lathers, Director of New Animal Drug Evaluation

Dr. Linda Tollefson, Director of the Office of Surveillance and Compliance